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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,365	01/18/2002	Mayumi Kotani	SAEGU92.001APC	7977

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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
VANIK, DAVID L	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 03/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,365	KOTANI ET AL.	
	Examiner	Art Unit	
	David L. Vanik	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11-15,17-22 and 24-27* is/are pending in the application.

4a) Of the above claim(s) *25-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11-15,17-22 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Applicant's Amended Claims and Remarks filed on 12/12/2005.

As a result of Applicant's amendments, the *35 USC §102* rejections over WO 98/42188 ('188) is hereby **withdrawn**. As a result of Applicant's amendments, the *35 USC §103* rejections over US Patent 4,808,574 ('574) in view of Fukumoto et al (Antianaphylactic Effects of the Principal Compounds from the White Petals of *Impatiens balsamina* L., Phytoherapy Research, Vol. 10., 202-206 (1996) and JP110296561A ('561) are hereby **withdrawn**. However the *35 USC §102* rejections over US 5,808,574 ('574) are hereby **maintained**.

Election/Restrictions

Newly submitted claims 25-27 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The instant claim set did not encompass the limitation of a composition comprising persimmon leaf extract. Rather, consistent with the instant claim set as filed, the compositions as examined comprised kaempherol-3-glucoside. With respect to the newly added claim 25, a method of treating sneezing, nasal discharge, or nasal congestion was not

contemplated in the original claim set. As such, claim 25 is drawn to non-elected subject matter.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 25-27 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

MAINTAINED REJECTIONS:

The following is a list of maintained rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 18-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 4,808,574 ('574).

'574 disclose a medicinal composition comprising kaempferol-3-glucoside (column 2, line 61). The kaempferol-3-glucoside-based compositions further comprise a carrier, ethanol (Claims 1 and 2). According to '574, kaempferol-3-glucoside can be combined with a food product, an alcoholic beverage (Claims 1 and 2). The treatment of pollinosis is considered a future intended use and, as such, is given no patentable weight in a composition claim.

Claims 21 and 22 are product-by-process claims. As such, claims 21 and 22 will be treated as product claims and not as method claims. By disclosing a composition comprising kaempferol-3-glucoside, the composition advanced by '574 anticipates the instant claims 21 and 22 (column 2, line 61).

The claims are therefore anticipated by US Patent 4,808,574 ('574).

Response to Arguments

Applicant's arguments filed on 12/12/2005 have been fully considered but they are not persuasive. In response to the 6/10/2005 Non-Final Rejection, Applicant has asserted that the '579 patent does not disclose the specific unit dosage as set forth in the amended claim 1. The examiner respectfully disagrees with this assertion.

As set forth in the abstract, 81-99 mg/kg of flavonols can be used in the instant invention. This falls within the range of from about 0.24 mg to about 210 mg enumerated in the amended claim 1. As such, it is the examiner's position that the instant claims 1, 18-22 are anticipated by US Patent 4,808,574 ('574).

Applicant's arguments with respect to claims 11-15, 17, and 24 have been considered but are moot in view of the new ground(s) of rejection. Specifically, the amount of kaempferol-3-glucoside per kg of body weight set forth in '574 appears to be substantially larger than the amount claimed in the instant application.

NEW REJECTIONS:

The following is a list of new rejections:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 11-15, 17-22, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As amended claims, 1, 17, and 24 introduce new matter.

With respect to claim 1, the dosage amount of from about .24 mg to about 210 mg is not supported by the instant disclosure. Specifically, Example 5 on page 28 of the instant specification discloses administering .24 mg of astragalin to individuals twice a

day (for a total of .48 mg). There is nothing that indicates that any other amount is effective at treating pollinosis. Additionally, there is nothing that indicates that this amount can be altered depending on the body weight of the individual. As such, the range of about .24 mg to about 210 mg is not supported by the instant disclosure and is considered new matter.

With respect to claims 17 and 24, the dosage amount of from about .48 mg per day per kg of body weight to either 1.5 or 3 mg per day per kg of body weight is not supported by the instant disclosure. As set forth on page 16, lines 22-25 of the instant disclosure, a range of 0.025 to 3 mg per kg of body weight is enumerated. The instant specification has not disclosed rage of .48 mg per day per kg of body weight to either 1.5 or 3 mg per day per kg of body weight. As such, the range of about .48 mg per day per kg of body weight to either 1.5 or 3 mg per day per kg of body weight is not supported by the instant disclosure and is considered new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1, 17-22 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,478,579 ('579)

'579 disclose medicinal compositions comprising kaempferol-3-glucoside (column 2, line 60). Between 50 mg to 250 mg of the glycoside, such as kaempferol-3-glucoside, can used in the instant formulation (column 2, lines 1-7). The kaempferol-3-glucoside-based compositions can further comprise a carrier, such as water (column 4, lines 29-43). According to '579, kaempferol-3-glucoside can be combined with a variety of other excipients and fillers (column 4, lines 29-42). The treatment of pollinosis is considered a future intended use and, as such, is given no patentable weight in a composition claim.

Claims 21 and 22 are product-by-process claims. As such, claims 21 and 22 will be treated as product claims and not as method claims. By disclosing a composition comprising kaempferol-3-glucoside, the composition advanced by '579 anticipates the instant claims 21 and 22 (column 2, line 61).

The claims are therefore anticipated by US Patent 5,478,579 ('579).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at (571) 272-0588. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
Art Unit 1615

2/26/06

CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500